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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/608,918	06/30/2000	Scott R. Presnell	99-50	2697

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/28/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/608,918

Applicant(s)

PRESNELL ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED OFFICE ACTION

Applicant's amendment in paper No. 14, filed on 17 December 2002 is acknowledged and entered. Following the amendment, the original claims 1-20 are canceled, and the new claims 21-44 are added.

Currently, claims 21-44 are pending and under consideration.

The declaration under 37 CFR 1.132 filed on 17 December 2002 (paper No. 14) is acknowledged, and it is insufficient to overcome the utility rejection and enablement rejection of claims 1-7 and 17, which are now represented by claims 21-44, under 35 U.S.C. 101 and 112, first paragraph, for the reasons addressed under "*Objections and Rejections under 35 U.S.C. §101 and §112*" below.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 1-7 and 17 are moot as the applicant has canceled the claims.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-44 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, and specific, or a well-established utility, for the reasons applied to the original claims 1-7 and 17, and set forth in the last Office Action, paper No. 11, mailed on 17 June 2002, at pages 2-5.

Applicants argument, and the declaration filed on 17 December 2002 (paper No. 14) have been fully considered, but are not deemed persuasive for reasons below.

Claims 21-44 are directed to a polypeptide having SEQ ID NO:2 or 10 (Zcytor14), and variants and fragments thereof. Based on the sequence homology of the polypeptide to a known

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protein, IL-17R, the specification asserts that the polypeptide having Zcytor14 activity can be used to treat inflammation and conditions such as rheumatoid arthritis, as IL-17 is known to play a pivotal role in initiating or sustaining an inflammatory response (page 70, the third paragraph). However, the specification fails to provide specific support for the asserted utility, such as information about a particular functional activity, biological significance of Zcytor14 polypeptide, or any known ligand for the putative cytokine receptor of the instant invention.

At pages 5-6 of the response, the applicants indicate that in support of a patentable utility, Applicants have submitted a declaration under 37 CFR 1.132, and further elaborate the content of the declaration. The declaration has been carefully reviewed by the Examiner, and is not found persuasive for the following reasons.

The declaration under 37 CFR 1.132 filed on 17 December 2002 (paper No. 14) indicates that based on a result of the experimental evidence (paragraphs 5, 6, 9 and 10), the Zcytor14 polypeptides as claimed are able to initiate or sustain the inflammatory process by up-regulating IL-17R, and a soluble Zcytor14 receptor is able to inhibit inflammation by suppressing the inflammatory effects of IL-17 by inhibiting its up-regulation of IL-6 and IL-8, thus, Zcytor14 has a specific, credible and substantial real-world use (paragraph 11). However, for the following reasons, the Examiner is not able to draw the same conclusion as that in paragraph 11 of the declaration.

The paragraph 9 states that Exhibit A shows that the addition of soluble Zcytor14 receptor was able to reduce to background levels the up-regulation of IL-6 in NHBE cells caused by the addition of IL-17. Based on the limited information provided regarding the detail of experimental procedure, the Examiner interprets that the inhibition effect of IL-6 production by the addition of soluble Zcytor14 seems to be through neutralizing IL-17, which causes the up-regulation of IL-6. If that is the case, the logic would dictate that the addition of the soluble IL-17R should have achieved the same result since IL-17 is the natural ligand of IL-17R, and should serve as a positive control in the experiment. However, the experimental data show the otherwise, that is the soluble IL-17R has no effect on the up-regulation of IL-6 in NHBE cells caused by the addition of IL-17. Such a result is confusing and suspect. While the applicant is not required to understand the underlying mechanism of the experimental

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result, the Examiner is not able to explain or reconcile the alleged result in the way to support the conclusion in paragraph 11 of the declaration at this point. Further, based on the result in the declaration, it is IL-17, not Zcytor14, that caused the up-regulation of IL-6, and there is no direct evidence indicating that IL-17 binds to Zcytor14 receptor. Therefore, it is unlikely that *Zcytor14* initiates inflammation as claimed. The same reasoning applies to the experimental result shown in Exhibit B, which measures the changes of IL-8 in the same experimental procedure as that in Exhibit A. For the reasons addressed above, the declaration is not persuasive, and the rejection under 35 U.S.C. 101 for lack of utility is, therefore, maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-44 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial, and specific asserted utility or a well established utility for the reasons applied to the original claims 1-7 and 17, setting forth in the last Office Action, paper No. 11, at page 5, and for the reasons above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion:

No claim is allowed.

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Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
2/21/03


LORRAINE SPECTOR
PRIMARY EXAMINER